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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/437,912	11/09/1999	KEITH R. MCCRAE	6056-257	8628
23973	7590	08/09/2002	EXAMINER	
DRINKER BIDDLE & REATH ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			ROBINSON, HOPE A	
ART UNIT		PAPER NUMBER		
1653		18		
DATE MAILED: 08/09/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/437,912</b>	Applicant(s) <b>McCrae</b>
Examiner <b>Hope Robinson</b>	Art Unit <b>1653</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jul 5, 2002

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-4, 8, 9, 16, 19, 22, and 30-49 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-4, 8, 9, 19, 22, and 30-35 is/are rejected.

7)  Claim(s) 16 and 36-49 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). 17

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other:

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## **DETAILED ACTION**

1. The finality of the previous office action has been withdrawn as claims 30-35 have been rejoined with the elected invention based on applicant's request.
2. Applicant's response to the Office Action mailed May 2, 2002 in Paper No. 16 on July 5, 2002 is acknowledged.
3. Claims 2 and 16 have been amended. Claims 1-4, 8-9, 16, 19, 22, 30-49 are pending.
4. The following grounds of rejection are or remain applicable :

### ***Claim Objection***

5. Claim 30 is objected to because the claim recites the formula "X<sub>1</sub>-His-Lys-X-Lys-X<sub>2</sub>" and there is no corresponding SEQ ID NO: for the entire sequence. It is noted that X1 represents SEQ ID NO:1 and X2 represents SEQ ID NO:2, however, once the sequence is attached to -His-Lys-X-Lys, what is the corresponding sequence identifier? See also claims 1, 16 and the dependent claims hereto.

Compliance with the sequence rules is required.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19, 22, 30-35, 41 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 22 are indefinite because the claims appear to be missing the article “a” where it is recited “effective amount of two-chain high molecular weight kininogen” or “effective amount of single-chain....”. It is suggested that the claims are amended to recite “effective amount of a two-chain high molecular weight kininogen”, for example.

Claim 30 is indefinite because the claim recites a compound of the formula X<sub>1</sub>-His-Lys-X-Lys-X<sub>2</sub> and there is no indication of what “X” stands for. It is noted that the dependent claim 31 states that X can be Asn, Phe or His, however, independent claim 30 has to stand on its own, and the metes and bounds of the claim are unknown without the definition of “X”. The claim is also indefinite as to the recitation of “and/or”, as it is unclear as to whether the slash mark refers to “and” or just “or”.

Claim 33 lacks antecedent basis as X is not defined in claim 30 and the sequence recited in claim 33 has X as being Phe.

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Claim 34 recites “the compound having the amino acid sequence....” and it appears that this claim was intended to depend from an independent claim not identified, thus indefinite (see also claim 35). If the claims are intended to be independent is this compound the same as recited in the preceding claims?

Claim 41 is indefinite for the recitation of “at least about” as the phrase “about” is broader and goes out side the narrower range of “at least” (see also claim 46).

#### *Claim Rejections - 35 U.S.C. § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 8-9 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferreira et al. (WO 97/05258, February 13, 1997) based on a formula wherein X is any amino acid, X<sub>1</sub> is a fragment thereof containing at least one amino acid and X<sub>2</sub> is zero amino acids.

Ferreira disclose peptides for use in diagnostic and therapeutic methods. Ferreira disclose the sequence contained in claim 1 in SEQ ID NO: 113, where the sequence is Glu-Ala-Pro-His-Lys-Phe-Lys-Asn-Val which means that X is Phe (as in claims 3 and 4 ), X<sub>1</sub> is a fragment and X<sub>2</sub>

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is two amino acids. The sequence disclosed by Ferreira also meets the limitation of claim 2 which requires  $X_1$  and  $X_2$  to be from zero to six amino acids or zero amino acids. Thus, the limitations of the claims are met by this reference.

8. Applicant's arguments filed July 5, 2002 was not sufficient to over come the rejections of record under 35 U.S.C. 102. Note that new rejections have been made under 35 U.S.C. 112, second and 102 (b) based on the rejoinder of claims 30-35. Regarding the rejection under 35 U.S.C. 102, applicant contends that claim 1 recites the minimum sequence of Gly-His-Lys-X-Lys because  $X_1$  must always contain at least one amino acid "Gly" and as the Ferreria reference teaches Pro it does not anticipate the claimed invention. This contention is not accurate as page 9 of the specification indicates that "N-terminal truncation fragment" means a fragment obtained from a parent sequence by removing one or more amino acids from the N-terminus thereof, thus, the "or more amino acids" of the definition could result in only one amino acid remaining in the N-terminus the claim does not specify what amino acid residue the one has to be. Thus applicant's statements that a Gly remains is not convincing. The reasoning is applied to newly rejected claims 30-32. Thus, the rejection remains.

*Conclusion*

9. No claims are presently allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner

  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER